

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., and ENDO
PAR INNOVATION COMPANY, LLC

C.A. No. 23-866-JLH-LDH

Plaintiffs,

v.

ZYDUS PHARMACEUTICALS (USA) INC.
and ZYDUS LIFESCIENCES LTD.

Defendants.

JOINT CLAIM CONSTRUCTION CHART

Pursuant to the Scheduling Order (D.I. 57), Plaintiffs Par Pharmaceutical, Inc., and Endo Par Innovation Company, LLC (collectively, “Plaintiffs” or “Par”) and Defendants Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Ltd. (collectively, “Defendants” or “Zydus”) submit this Joint Claim Construction Chart identifying the claim terms at issue for U.S. Patent Nos. 11,717,524 (the “‘524 patent”) and 11,779,587 (the “‘587 patent”), each party’s proposed constructions, and each party’s citations to the intrinsic evidence in support of the proposed constructions of the claim terms of the ’524 and ’587 patents. A copy of the ’524 and ’587 patents (Exhibit A-B) and portions of the intrinsic record relied upon (Exhibits C-N) are attached hereto.

The parties reserve the right to rely on additional intrinsic evidence to the extent it is necessary to provide additional context or to rebut arguments made by other parties during the claim construction briefing. The parties further reserve the right to rely on any intrinsic evidence

by any other party. The parties reserve the right to update and/or supplement their proposed claim constructions with the *Markman* briefing in this case. By agreeing to a construction or proposing a construction of any term, Defendants do not waive any defense under 35 U.S.C. § 112.

The parties intend to rely on the '524 and '587 patents, the specifications of the '524 and '587 patents, the claims of the '524 and '587 patents, the file histories of the '524 and '587 patents, and patents and applications to which the '524 and '587 patents claim priority or which claim priority to the '524 and '587 patents. Any citation to intrinsic evidence provided by the parties in support of their proposed claim constructions is intended as exemplary. Any additional evidence or reference within or encompassed by a particular citation is deemed incorporated by reference (e.g., cited passages are intended to include all figures and tables referenced therein). The parties also reserve the right to rely on extrinsic evidence and/or expert declaration or testimony in support of their proposed constructions or to rebut the other party's arguments and/or any expert declaration or testimony submitted by the other party.

I. Each Parties' Proposed Construction of Each Disputed Term of the '524 and '587 Patents

The parties dispute the construction of the following terms of the '524 and '587 claims.

Par proposes no terms for construction, and it is Defendants who seek to deviate from the plain and ordinary meaning of the terms. Thus, Defendants must explain why resolution of each dispute matters.

Defendants offer their proposed constructions to align with the intrinsic evidence. The proper constructions of the terms identified herein bear on non-infringement and invalidity of the asserted claims in the '524 and '587 patents.

Claim Term	Zydus Proposed Construction	Zydus Intrinsic Evidence	Par Proposed Construction	Par's Intrinsic Evidence
“means for reducing the nitrosamine impurities” (‘524 patent, claim 1)	“means for reducing the amounts of the nitrosamine impurities, wherein the amounts of nitrosamine impurities are decreased by the means”	<p>The '524 patent. <i>See e.g.</i>, '524 patent at claims; '524 patent at 13:16-25; 14:20-55; 15:58-17:17 and Table 3; Figs. 1 and 11; 21:10-52; 22:19-30; 37:53-42:35; 65:51-68:67 and Table 23.</p> <p>U.S. Application No. 17/930,824 (“the ‘824 application”) file history, Sept. 9, 2022, Claims; Jan. 18, 2023, Non-Final Rejection; Mar. 29, 2023, Amendment and Remarks; Apr. 17, 2023, Applicant-Initiated Interview Summary; Apr. 18, 2023, Supplemental Amendment and Remarks; May 12, 2023, Final Rejection; May. 18, 2023, Amendment and Remarks; June 7, 2023, Notice of Allowability.</p>	<p>Plain and ordinary meaning</p> <p>To the extent the court requires a construction, “a step or steps taken to contribute to the reduction of nitrosamine impurities,” as defined later in the claim.</p> <p>(To the extent Zydus’s construction would require a single means for reducing nitrosamine impurities, the claim is not so limiting.)</p>	Support is found at least at: '524 patent, claim 1, 6, 12, 18, 20, 26, 1:61-3:2, 12:60-17:18; 37:53-42:35, 65:1-69:15.
“an acid-base treatment” (‘524 patent, claims 1, 12, 18, and 26)	Indefinite To the extent the court requires a construction, “an acid-base treatment	A POSA reading the specification and prosecution history would not, with reasonable certainty, be able to ascertain the meaning of the claim limitations reciting “an	<p>Not indefinite; plain and ordinary meaning</p> <p>To the extent the court requires a construction, “a</p>	Support is found at least at: '524 patent, claims 1, 6, 12, 13, 18, 20, 26, 13:16-25, 14:9-34, 15:58-16:16.

Claim Term	Zydus Proposed Construction	Zydus Intrinsic Evidence	Par Proposed Construction	Par's Intrinsic Evidence
	that extracts the varenicline product into the aqueous phase while leaving the nitrosamine impurities in the organic phase”	<p>acid-base treatment.” <i>See Nautilus, Inc. v. Biosig Instruments, Inc.</i>, 572 U.S. 898, 910 (2014).</p> <p>The '524 patent. <i>See, e.g.</i>, '524 patent at claims; '524 patent at 13:16-25; 14:20-55; 15:58-17:17 and Table 3; Figs. 1 and 11; 21:10-52; 22:19-30; 37:53-42:35; 65:51-68:67 and Table 23.</p> <p>'824 application file history, Sept. 9, 2022, Claims; Jan. 18, 2023, Non-Final Rejection; Mar. 29, 2023, Amendment and Remarks; Apr. 17, 2023, Applicant-Initiated Interview Summary; Apr. 18, 2023, Supplemental Amendment and Remarks; May 12, 2023, Final Rejection; May. 18, 2023, Amendment and Remarks; June 7, 2023, Notice of Allowability.</p>	process to separate a desired substance from an undesired substance via treatment with an acid and subsequent treatment with a base.”	

Claim Term	Zydus Proposed Construction	Zydus Intrinsic Evidence	Par Proposed Construction	Par's Intrinsic Evidence
“means for removing the nitrosamine impurities” (‘524 patent, claim 12)	“means for removing the nitrosamine impurities, wherein the nitrosamine impurities are removed by the means”	<p>The '524 patent. <i>See, e.g.</i>, '524 patent at claims; '524 patent at 13:16-25; 14:20-55; 15:58-17:17 and Table 3; Figs. 1 and 11; 21:10-52; 22:19-30; 37:53-42:35; 65:51-68:67 and Table 23.</p> <p>'824 application file history, Sept. 9, 2022, Claims; Jan. 18, 2023, Non-Final Rejection; Mar. 29, 2023, Amendment and Remarks; Apr. 17, 2023, Applicant-Initiated Interview Summary; Apr. 18, 2023, Supplemental Amendment and Remarks; May 12, 2023, Final Rejection; May. 18, 2023, Amendment and Remarks; June 7, 2023, Notice of Allowability.</p>	<p>Plain and ordinary meaning</p> <p>To the extent the court requires a construction, “a step or steps taken to contribute to the removal of nitrosamine impurities” as defined later in the claim.</p> <p>(To the extent Zydus’s construction would require a single means for removing nitrosamine impurities or that the means remove all nitrosamine impurities, the claim is not so limiting.)</p>	Support is found at least at: '524 patent, claim 1, 6, 12, 18, 20, 26, 1:61-3:2, 12:60-17:18; 37:53-42:35, 65:1-69:15.
“employing an acid-base treatment to remove the nitrosamine impurities” (‘524 patent,	“employing an acid-base treatment to remove the nitrosamine impurities, wherein the nitrosamine impurities are	<p>The '524 patent. <i>See, e.g.</i>, '524 patent at claims; '524 patent at 13:16-25; 14:20-55; 15:58-17:17 and Table 3; Figs. 1 and 11; 21:10-52; 22:19-30; 37:53-42:35; 65:51-68:67 and Table 23.</p>	<p>Plain and ordinary meaning</p> <p>To the extent the court requires a construction, “employing a process</p>	Support is found at least at: '524 patent, claim 1, 6, 12, 13, 18, 20, 26, 1:61-3:2, 12:60-17:18; 37:53-42:35, 65:1-69:15.

Claim Term	Zydus Proposed Construction	Zydus Intrinsic Evidence	Par Proposed Construction	Par's Intrinsic Evidence
claims 18 and 26)	removed by the acid-base treatment”	<p>42:35; 65:51-68:67 and Table 23.</p> <p>’824 application file history, Sept. 9, 2022, Claims; Jan. 18, 2023, Non-Final Rejection; Mar. 29, 2023, Amendment and Remarks; Apr. 17, 2023, Applicant-Initiated Interview Summary; Apr. 18, 2023, Supplemental Amendment and Remarks; May 12, 2023, Final Rejection; May. 18, 2023, Amendment and Remarks; June 7, 2023, Notice of Allowability.</p>	to separate a desired substance from nitrosamine impurities via treatment with an acid and subsequent treatment with a base to contribute to the removal of nitrosamine impurities.”	
“0.15% (w/w)” (‘587 patent, claims 1, 13, and 24)	<p>Indefinite</p> <p>To the extent the court requires a construction, “0.15% (w/w) of [impurity]/Varenicline Tartrate Maltodextrin premix (1:10)”</p>	<p>A POSA reading the specification and prosecution history would not, with reasonable certainty, be able to ascertain the meaning of the claim limitations reciting “0.15% (w/w).” <i>See Nautilus</i>, 572 U.S. at 910.</p> <p>The ’587 patent. <i>See e.g.</i>, ’587 patent at claims; ’587 patent</p>	<p>Not indefinite; Plain and ordinary meaning</p> <p>To the extent the court requires a construction, “0.15% (weight of one substance divided by weight of another substance)” each of the claims identified by Zydus specify</p>	<p>Support is found at least at: ’587 patent, claims 1, 13, 24, and 28, 6:1-4, 14:55-65, 23:17-33, 24:8-28, 49:18-68:49, 72:54-73:19.</p> <p><i>See also</i>, e.g., Chantix April 2010 Highlights of Prescribing Information for its Varenicline Tablets; Par’s July 2021 Highlights of Prescribing Information for its Varenicline</p>

Claim Term	Zydus Proposed Construction	Zydus Intrinsic Evidence	Par Proposed Construction	Par's Intrinsic Evidence
		2:6-42; 2:64-3:2; 3:3-8; Fig. 4, 5, 7; 7:15-34; 17:43-22:29; 23:10-12; 23:34-36; Table 5 (cols 29-32); 24:8-28; 35:34-37; 38:5-9; 50:16-24; 51:44-45; Table 14; 55:29-59:28; Tables 19-21; examples 1-5.	what the substances are.	Tablets; “Apo-Varenicline—varenicline tablet, film coated,” Apotex Corp., Important Prescribing Information dated July 2, 2021; “Control of Nitrosamine Impurities in Human Drugs—Guidance for Industry”, dated Sept. 2020; FDA “Liquid Chromatography-High Resolution Mass Spectrometry (LC-ESI-HRMS) Method for the Determination of Varenicline Nitroso-Drug Substance Related Impurity (NDSRI) in Chantix™ Drug Product and Varenicline Drug Substance” dated August 6, 2021; “FDA Updates and Press Announcements on Nitrosamine in Varenicline (Chantix)”, dated July 30, 2021; “FDA Updates and Press Announcements on Nitrosamine in Varenicline (Chantix)”, dated May 5, 2022; ICH Harmonised Tripartite Guidelines, “Impurities in New Drug Substances Q3A(R2)”; “Assessment Report –

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				<p>Procedure under Article 5(3) of Regulation EC (No) 726/2004 – Nitrosamine impurities in human medicinal products,” European Medicines Agency—Committee for Medicinal Products for Human Use (CHMP), dated June 25, 2020; FDA “Laboratory analysis of varenicline products” dated Feb. 8, 2022.</p> <p>Support can also be found in the file history of the '587 patent, including the July 11, 2023 Amendment and Response to Non-Final Action. Par reserves the right to rely on this or any other portion of the '587 patent file history.</p>
“as measured by [method]” ('524 patent, claims 1 and 18; '587 patent, claims 1, 13, and 24)	Should be construed similar to the “product-by-process claims”. <i>See</i> MPEP 2113 (“[E]ven though product-by-process claims are limited by and defined by the process,	The '524 patent. <i>See e.g.</i> , '524 patent at claims; '524 patent at 2:1-6; 3:16-23; 3:43-46; 6:59-67; 9:35-61; 11:66-12:21; 15:5-40; 20:1-21:9; 21:53-22:65; 46:35-63:37; Table 22.	Not product-by-process claims. The claims do not require the accused infringer to use the methods recited in the claims to measure the impurity.	Support is found at least at: '524 patent, claims 1 and 18; '587 patent claims 1, 13, and 24. '587 patent, 50:5-60:49 (and corresponding disclosure from '524 patent).

Claim Term	Zydus Proposed Construction	Zydus Intrinsic Evidence	Par Proposed Construction	Par's Intrinsic Evidence
	<p>determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” <i>In re Thorpe</i>, 777 F.2d 695, 698 (Fed. Cir. 1985)) (citations omitted).</p>	<p>The '587 patent. <i>See e.g.</i>, '587 patent at claims; '587 patent at 2:1-5; 3:16-23; 3:43-46; 9:58-10:17; 12:24-51; 15:51-16:20; 21:10-22:29; 23:27-24:41; 49:19-68:50; Table 22.</p> <p>'824 application file history, Jan. 18, 2023, Non-Final Rejection.</p> <p>U.S. Application No. 18/148,659 (“the '659 application”) prosecution history, Apr. 17, 2023, Non-Final Rejection.</p>		<p><i>See also, e.g.</i>, FDA “Liquid Chromatography-High Resolution Mass Spectrometry (LC-ESI-HRMS) Method for the Determination of Varenicline Nitroso-Drug Substance Related Impurity (NDSRI) in Chantix™ Drug Product and Varenicline Drug Substance” dated August 6, 2021</p>

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